

REMARKS

Claims 1-12, 15-21, and 26-38 are pending in the application.

Claims 1-12, 15-21, and 26-38 are finally rejected.

Claims 1 and 18 are currently amended.

Claims 19 is previously amended.

Claims 2-12, 15-17, 20, 21, and 26-38 are original.

Claims 1-12, 15-21, and 26-38 are directed to a method for improving functional health status, and would be all of the claims remaining in the application if the instant amendment is entered. Please replace the currently pending claim set with the above claim set.

Discussion of Amendment

Claim 1 is amended to delete the phrase “age-related” and insert the phrase “resulting from aging.” This amendment is supported by the instant specification such as, for example, on page 5, at lines 29-31, on page 19, at lines 31-32, on page 29, at line 33, to page 31, at line 9. Particularly, note page 30, at lines 11-14, which discusses decline in physical performance as a result of aging and objective measures thereof. No new matter is added.

Claim 18 is amended to correct a typographical error in the spelling of the term “substituents” in the definition of group R¹¹. No new matter is added.

Applicants respectfully believe that the Examiner’s remarks on page 2 of the Office Action regarding the meaning of the phrase “age-related” constitute a misinterpretation of the meaning. Applicants continue to believe that the phrase “age-related” means a result of aging. Nevertheless, Applicants have amended the phrase to overcome what is respectfully seen as a problem of semantics.

Claim Rejections - 35 U.S.C. § 103

Claims 1-12, 15-21, and 26-38 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 00/12047 in view of WO 97/24369 as set forth in item nos. 6-8 of the Office Action mailed January 30, 2003.

Applicants note with pleasure that the rejection over WO 97/41879 in view of WO 97/24369 has been rendered moot by Applicants' previous amendment in their Amendment and Response under 37 CFR 1.111 dated June 26, 2003.

Applicants respectfully traverse the rejection over WO 00/12047 in view of WO 97/24369 for the reasons provided below.

WO 00/12047 describes a method for enhancing the return of a patient to independent living status following acute deconditioning which comprises administering to the patient an effective amount of a growth hormone secretagogue ("GHS," see Claim 1). The first paragraph on page 1 of WO 00/12047 clearly describes such patients as those who have experienced acute deconditioning that resulted from a "major illness or injury," "surgery," or "acute illness." The acute deconditioning is not contributed by age, as the Examiner alleged in the Office Action, although the patient having acute deconditioning may be elderly. WO 00/12047 describes a complication of acute deconditioning in the elderly as relating to prolonged recovery times, but the acute deconditioning is still the result of major illness or injury, "surgery," or "acute illness. Thus WO 00/12047 teaches enhancing the return of a patient of any age to independent living status by administration of a GHS to said patient to treat the deconditioning effects of acute physical trauma to said patient's body.

WO 97/24369 describes certain active compounds of the instant method as GHS's.

Instant Claims 1-12, 15-21, and 26-38 are directed to a method for improving functional health status in a patient with decline in physical performance resulting from aging, which comprises administering to the patient a therapeutically effective amount of a GHS. Instant Claims 1-12, 15-21, and 26-38 are thus directed to improving *physical* performance that has declined as a *result* of aging.

The instant invention method is directed to patients that have experienced a chronic, general physical decline that is a direct result of aging, and not a result of acute injury, major illness, or other medical trauma. At the time of filing the instant application, conventional medical wisdom had it that decline in physical performance resulting from aging was irreversible. In fact for hundreds of years, adventurous souls have searched in vain for the proverbial fountain of youth.

The gist of the Examiner's reasoning for the rejection in the Office Action seems to be that "age-related" conditions include not just physical decline caused by age, but also physical decline from causes that accompany aging, and thus it would allegedly be obvious to treat "age-related" physical decline with a GHS in view of WO 00/12047 and WO 97/24369. As amended, Claim 1 (and for that matter Claims 2-12, 15-21, and 26-38 dependent therefrom) clearly do not embrace physical decline from causes that accompany aging.

Further, there is no known commonality between physical deconditioning due to an acute medical event described in WO 00/12047 and physical decline due to aging. In WO 00/12047, a previously independent living patient is being treated so that the patient may return to that precedented status.

On the other hand at the time of filing the instant application, there was no expectation that patients experiencing physical decline due to aging could

experience improved health status. At that time, all people, not just one of ordinary skill in the medical art (“Skilled Artisan”), knew that aging unfailingly led to physical decline and eventually death by natural causes. No one would have reasonably expected that physical decline resulting from aging was reversible.

Thus while WO 00/12047 in view of WO 97/24369 arguably may have provided motivation to the Skilled Artisan to try using a GHS for improving the health status of patients experiencing physical decline due to aging, the Skilled Artisan could not have had a reasonable expectation of success given humankind’s ingrained beliefs about aging. Accordingly, a *prima facie* case of obvious has not been established for the obviousness rejection of Claims 1-12, 15-21, and 26-38 over WO 00/12047 in view of WO 97/24369. Claims 1-12, 15-21, and 26-38 are thus patentable under 35 U.S.C. § 103(a).

In view of the amendment to Claim 1 and the above remarks, Applicants respectfully request removal of WO 00/12047 in view of WO 97/24369 as grounds for rejection of Claims 1-12, 15-21, and 26-38 under 35 U.S.C. § 103(a). Applicants respectfully request reconsideration of Claims 1-12, 15-21, and 26-38, and advancement of all patentable claims to allowance.

The Commissioner is hereby authorized to charge any fees that may be required to continue prosecution of this case, including a fee for an extension of time, or credit any overpayment, to deposit account number 23-0455.

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Respectfully submitted,

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